

REMARKS

Status of the Claims.

Claims 1-4, 6-10, 20-29, and 31 are pending with entry of this amendment, claims 5, 11-19, and 30 being cancelled and no claims being added. Claim 1 is amended herein. This amendment introduces no new matter, but merely makes a grammatical correction.

Withdrawal of rejections.

Applicants note with appreciation the withdrawal of rejections of claims under 35 U.S.C. §112, first paragraph, and under 35 U.S.C. §102(b) made in the previous Office Action.

35 U.S.C. §112, First Paragraph.

Claims 1-4, 6-10, 20-29, and 31 were rejected under 35 U.S.C. §112, first paragraph. In particular, the Examiner alleged that "[t]he specification is not enabling for a method of increasing the efficacy of a gastric H⁺/K⁺-ATPase inhibitor (PPI) in a human in need of a PPI by administering an effective amount (e.g., 0.1-10 mg/kg/hr) of a pentagastrin, a gastrin, or a gastrin analog with the PPI." (*see, e.g.*, Office action, page 3). In support of her argument, the Examiner alleged that "... because the specification only discloses cursory conclusions without data supporting the findings ... there are no indicia that the present application enables the full scope of the claim. . . ". (*see, e.g.*, Office action, page 3). The Examiner further alleged, that "... the specification has not demonstrated an effective amount (0.1-10 mg/kg/hr) of a gastrin, a pentagastrin, or an analog of gastrin increases the efficacy of a PPI as compared to the activity of PPI alone. (*see, e.g.*, Office action, page 6). In short, the Examiner alleges that Applicants have not provided data to establish that the claimed methods work and it would therefore require undue experimentation to practice the claimed methods. Applicants traverse.

The Examiner's attention is drawn to the accompanying abstract (Barda *et al.* (2004) *Supplement to Gastroenterology*, 12(4): Suppl. 2, Abstract M1439, designated Exhibit A). In that abstract the authors state:

These data indicate that **prestimulation of gastric proton pumps with oral PG [pentagastrin] enhances the inhibitory effect of omeprazole** [a PPI] on acid secretion. This effect is mediated by a local effect of PG. **Co-administration of PG and omeprazole may be used clinically to potentiate the therapeutic effect of omeprazole.** [emphasis added]

Published scientific literature thus clearly establishes that pentagastrin can be used in either a pre-stimulatory mode or coadministered with a PPI to enhance the activity of that PPI. Moreover, the scientific literature further establishes that the effect is clinically relevant.

The claimed methods clearly work and indeed, have clinical value. In view of this showing no undue experimentation is required to practice the claimed invention. Accordingly the rejection of claims 1-4, 6-10, 20-29, and 31 under 35 U.S.C. §112, first paragraph, should be withdrawn.

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. Should the Examiner seek to maintain the rejections, Applicants request a telephone interview with the Examiner and the Examiner's supervisor.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 769-3513.

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Respectfully submitted,



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